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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,150	06/24/2003	Robin Callan	100070.401C1	3537

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,150	CALLAN ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a **precursor** composition for preparing a buffered dialystate, the precursor composition comprising citrate at a concentration ranging from about 20 to about 900 meq/L; a buffer; water; **chloride** at a concentration ranging from about **1,000 to about 7,000 mEq/L**; and at least one physiologically-acceptable cation, classified in class 210, subclasses 646, 647.

II. Claims 16-25 and 51-53 drawn to a buffered dialysate composition comprising treated water; **chloride** at a concentration ranging from about **20 to about 200mEq/L**; citrate at a concentration ranging from about 0.5 to about 30 mEq/L; a buffer; base including bicarbonate; and at least one physiologically-acceptable cation, classified in class 210, subclasses 646, 647.

III. Claims 26-38 and 46, drawn to a method of forming a dialysate precursor composition comprising mixing treated water, chloride, citrate, at least one buffering anion selected from acetate and/or lactate, and at least on physiologically-acceptable cation to provide a composition having chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L, citrate at a concentration ranging from about 20 to about 900 mEq/L, and at least

one buffering anion selected from acetate and lactate at a concentration ranging from about 0.01 to about 150mEq/L and a composition prepared, classified in class 424, subclass 665.

IV. Claims 39-45 and 47 drawn to a method of forming a buffered dialysate composition comprising mixing a dialysate precursor composition with an aqueous bicarbonate-containing solution, the dialysate precursor composition comprising treated water, chloride, citrate, at least one buffering anion selected from acetate and lactate, and at least one physiologically-acceptable cation to provide a dialysate composition having chloride at a concentration ranging from about 44 to about 143 mEq/L, citrate at a concentration ranging from about 1.5 to about 30mEq/L, and at least one buffering anion selected from acetate and lactate at a concentration ranging from about 0.01 to about 3.6 mEq/L and composition prepared, classified in class 424, subclass 665.

V. Claims 48-50, drawn to an aqueous acid-concentrate composition comprising water, chloride at a concentration of about 1,000 to about 7,000 mEq/L; citrate at a concentration ranging from about 20 to about 900 mEq/L; and sufficient physiologically acceptable cations to provide for a neutral composition, wherein the composition has a pH of less than 4; and **does not contain** any of acetate, bicarbonate or lactate, classified in class 210, subclasses 646, 647.

VI. Claims 54-56, drawn to a method for performing dialysis comprising combining a first solution with a second solution to form dialysate, and performing hemodialysis with the dialysate, the first solution comprising citrate, buffer and water, the second solution comprising bicarbonate and water, classified in class 210, subclass 646, 647.

The inventions are distinct, each from the other because of the following reasons:

Inventions Groups I&II and Groups III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product since the product of Group I can be used for precursor agent to prepare a parenteral injectables including intramuscular, intravenous, subcutaneous administration; Group II can be used for hypokalemia.

Inventions Groups I, II &V and Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product

since the product of Groups I, II &V can be used for means other than performing dialysis since the products can be use as total parenteral nutritional solution precursor and a injectable carrier.

Inventions Groups I and Groups II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operations and effects because Groups I &II requires high amount of Chloride concentration having different operation and must be diluted prior to human use and also can be used as general bulk solution for various injectables including parenteral nutritional formulation while Groups II &IV requires less amount of Chloride concentration having different operation in human without the dilution step prior to use.

Inventions Groups III and Groups IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operations and effects because Groups III requires high amount of Chloride concentration having different operation and must be diluted prior to human use and also can be used as general bulk solution for various injectables including parenteral nutritional formulation while Groups IV requires less amount of Chloride concentration having different operation in human without the dilution step prior to use.

Inventions Group III &IV and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes operation because the Groups III & IV are requiring single step of mixing all the components together while Group VI requiring additional step of performing hemodialysis with the dialysate combining solutions that are already premixed.

Inventions Group I and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation and effects because Group I requires buffer to neutralized the resulting composition while Group V does not require buffer to neutralized the resulting composition of having pH less than 4.

Inventions Group II and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation and effects because Groups V requires high amount of Chloride concentration having different operation and must be diluted prior to human use and also can be used as general bulk solution for various injectables including parenteral nutritional formulation while Groups II requires less amount of Chloride concentration having different operation in human without the dilution step prior to injectable use.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and a serious burden would place on the Examiner to search all unrelated invention, restriction for examination purposes as indicated is proper.

Applicants are advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicants traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

> The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
>
> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 5:30 am to 2 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
June 26, 2006